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## कोलोन — विशिष्टि

( दूसरा पुनरीक्षण )

## Cologne — Specification

( Second Revision )

ICS 71.100.70

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## FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

This standard was published in 1977 and first revised in 1995. In the first revision, method of determination of alcohol content was revised and a list of suitable denaturants which was commonly used for alcoholic cosmetic preparation was included for manufacturers' reference. In addition, requirements for stability of perfume and transparency above 5°C were specified. In this revision, following major changes have been made:

- a) All the four amendments issued to its previous version (1995) have been appropriately incorporated,
- b) References see (2) have been updated, and
- c) Gas chromatographic method for determination of ethanol content (*see Annex A*) has been incorporated.

A cologne conventionally has a citrus refreshing note. For the purpose this standard, toilet waters, lavender waters and other alcohol-based fresheners are covered under cologne.

It is necessary that the raw materials used are such that in the concentrations in which they would be present in the finished cologne, after interaction with the other raw materials used in the formulation are free from any harmful effects. It shall be the responsibility of the manufacturers of cologne to satisfy itself of the safety of their formulation before releasing the product for sale.

A scheme for labelling environment friendly known as ECO-Mark has been introduced at the introduced at the Ministry of Environment and Forest (MEF), Government of India. The ECO-Mark is being administered by the *Bureau of Indian Standards Act, 2016* as per the Resolution No. 71 dated 21 February 1991 and No. 768 dated 24 August 1992 published in the Gazette of the Government of India. For a product to be eligible for marking with ECO logo, it shall also carry the Standard Mark of Bureau of Indian Standards besides meeting additional environment friendly requirements. For this purpose, the Standard Mark of Bureau of Indian Standards would be a single mark being a combination of the Bureau of Indian Standards monogram ISI and the ECO logo. Requirements of ECO friendliness will be additional, manufacturing units will be free to opt for Standard Mark alone also.

The composition of the Committee responsible for formulation of this standard is given at Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test of analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Indian Standard*

# COLOGNE — SPECIFICATION

*(Second Revision)*

## 1 SCOPE

This standard prescribes the requirements and methods of sampling and test for cologne. Toilet waters, lavender waters and all alcohol-based fresheners are covered in this standard.

## 2 REFERENCES

The following standards contain provisions which through reference in this text constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent revisions of the standards indicated below:

<i>IS No.</i>	<i>Title</i>
323 : 2009	Rectified spirit for industrial use — Specification ( <i>Second revision</i> )
3958 : 1984	Methods of sampling cosmetics ( <i>first revision</i> )
4011 : 2018	Methods of test for safety evaluation of cosmetic ( <i>third revision</i> )
4117 : 2008	Alcohol denaturants — Specification ( <i>second revision</i> )
4707	Classification for cosmetic raw materials and adjuncts
(Part 1) : 2017	Colourants ( <i>third revision</i> )
(Part 2) : 2017	List of raw materials generally not recognized as safe for use in cosmetics ( <i>fourth revision</i> )

## 3 REQUIREMENTS

### 3.1 Description

It shall be a clear aqueous ethanol solution containing perfume oil. It may contain emollients, antiseptic agents, denaturants, colouring agents, etc.

### 3.2 Ingredients

Unless specified otherwise, all the raw materials used in the manufacture of cologne shall conform to the requirements prescribed in the relevant Indian Standards where such standards exist. Alcohol used shall conform to IS 323.

**3.3** All the ingredients that go into formulation of cologne shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2).

**3.4** For safety evaluation of novel ingredients used in formulation of cologne, the cologne shall comply to IS 4011.

### 3.5 Alcohol Content

**3.5.1** The minimum alcohol content in the product shall be 50 percent (v/v), when tested as prescribed in Annex A.

**3.5.2** It shall be free from methanol when tested as prescribed in Annex A.

**3.5.3** List of suitable denaturants which are considered toxicologically safe for use in alcoholic cosmetic preparations is given in IS 4117.

### 3.6 Stability of Smell

**3.6.1** When tested in accordance with the test method as specified in **3.6.2**, after 12 h the smell of cologne shall be clearly picked up.

**3.6.2** Put some pieces of bleached gauze of dimensions 5 x 10 cm, which has been pre-washed in hot water without soap and dried, into a porcelain cup and pour 1.5 ml of cologne into this cup. After the gauze gets soaked take it out with the help of pincers and without squeezing it, dry it in a premise having temperature  $27 \pm 2^\circ\text{C}$ , humidity  $65 \pm 5$  percent. If after 12 h, the smell of cologne can be clearly picked up, the product shall be taken to have passed the test.

### 3.7 Cloud Temperature

**3.7.1** When tested in accordance with the test method as specified in **3.7.2**, at a temperature of  $5^\circ\text{C}$  the cologne shall be transparent.

**3.7.2** Pour 20 ml cologne into a wide cylinder and close it with a plug, into which insert a thermometer having scale upto  $20^\circ\text{C}$ . Immerse the thermometer into the liquid in such a manner that its bulb is situated at the same distance from the bottom and walls, immerse the cylinder containing liquid in a cooling mixture containing ice and salt. After cooling the sample to  $+5^\circ\text{C}$ , take out the cylinder, shake it and scan it in transmitted daylight or in the light of a 40 W electric

lamp. At a temperature of +5°C the product shall be taken to have passed the test if no turbidity appears.

### 3.8 Additional Requirements for ECO Mark

#### 3.8.1 General Requirements

**3.8.1.1** The product shall conform to the requirements for quality, safety and performance prescribed under **3.1 to 3.7**.

**3.8.1.2** All the ingredients that go into formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2).

**3.8.1.3** The product shall also meet specific requirements as given in the standard.

**3.8.1.4** The product package shall display a list of ingredients in descending order of quantity present.

**3.8.1.5** The product shall not be manufactured from any carcinogenic ingredients.

**3.8.1.6** The manufacturer shall produce to Bureau of Indian Standards the environmental consent clearance from the concerned State Pollution Control Board as per the provisions of the *Water (Prevention and Control of Pollution) Act, 1974*, the *Air (Prevention and Control of Pollution) Act, 1981* along with the authorization, if required under the *Environment (Protection) Act, 1980* and the Rules made thereunder, while applying for ECO Mark. Additionally, provisions of the *Drugs and Cosmetics Act, 1940* and the Rules thereunder shall also be complied with.

#### 3.8.2 Specific Requirements

**3.8.2.1** Product shall be dermatologically safe when tested as prescribed in IS 4011.

**3.8.2.2** Heavy metals calculated as lead (Pb) and arsenic ( $As_2O_3$ ) shall not exceed 10 and 1 ppm, respectively when tested as per the respective method prescribed in Indian Standards.

## 4 PACKING AND MARKING

**4.1** The cologne shall be packed in suitable well closed containers.

**4.2** For ECO Mark the product package shall be packed in such packages which shall be recyclable or biodegradable.

**4.3** The containers shall be legibly marked with the following information:

- a) Name of the material;

- b) Manufacturer's name and its recognized trademark, if any;
- c) Net volume;
- d) Batch number;
- e) Name and content of denaturant, if added;
- f) A caution sign given below:  
‘HARMFUL IF TAKEN INTERNALLY’;
- g) List the ingredients (at the time of manufacture) under the title ‘Ingredients’ as follows:
  - 1) For ingredients more than 1 percent (by mass or volume) — List the ingredients in decreasing order of percentage.
  - 2) For ingredients less than 1 percent (by mass or volume) — List the ingredients in any order.

NOTE — This is exempted in case of pack sizes less than 30 g of solid/semi-solid and 60 ml of liquid.
- h) ‘Use before..... (Month and year MM/YY, or months/years from the date of manufacture) to be declared by the manufacturer; and
- j) Any other information required by statutory authorities.

## 4.4 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the standard mark.

**4.5** The product package shall be suitably marked that ECO Mark label is applicable only to the contents, if the product package is not separately covered under the ECO Mark scheme

## 5 SAMPLING

**5.1** Representative samples of the material shall be drawn as prescribed in IS 3958.

**5.2** Test for all characteristics shall be carried out on the composite sample.

**5.3** The material shall be taken to have conformed to this standard if the composite sample passes all the tests.

## 6 QUALITY OF REAGENTS

**6.1** Unless specified otherwise, pure chemicals and distilled water (see IS 1070:1992- Reagent grade water) shall be used in tests.

NOTE — ‘Pure chemicals’ shall mean chemicals that do not contain impurities which affect the results of analyses.

## ANNEX A

( Clause 3.5.1 and 3.5.2 )

GAS CHROMATOGRAPHIC METHOD OF TEST FOR ALCOHOL CONTENT  
AND ABSENCE OF METHANOL IN COLOGNE

## A-1 DETERMINATION OF ALCOHOL CONTENT

## A-1.1 Apparatus

**A-1.1.1 Gas Chromatograph** — Equipped with Flame Ionization Detector (FID) and split injection port.

**A-1.1.1.1** Chromatographic conditions:

Column	Fused silica capillary column packed with 6 percent cyanopropylphenyl and 94 percent dimethyl polysiloxane
Film thickness	1.8 $\mu\text{m}$
Column dimension	30 m $\times$ 0.32 mm ID
Injector Temperature	200°C
Split ratio	1 : 40
Sample size	0.5 $\mu\text{l}$ (2 percent solution in suitable solvent)
Carrier gas and flow	Nitrogen or Helium, at the flow rate of about 1.2 ml/min
Column oven Temperature	60°C for 5 min, then raised to 150°C at a rate of 10°C per min
Detector type	<i>FID</i>
Hydrogen gas flow rate	30 ml/min
Air flow rate	300 ml/min
Detector temperature	250°C

NOTE — Optimum operating conditions may vary with column and instrument used and must be determined by using standard solutions. Adjust the parameters for maximum peak sharpness and optimum separation. With high level standard, 1-propanol should give almost complete baseline separation from ethanol.

## A-1.2 Reagents and Solutions

**A-1.2.1 Ethanol** — 99.9 percent (v/v), *Min*

**A-1.2.2 1-Propanol** — 99.9 percent (v/v), *Min*

**A-1.2.3 Methanol** — 99.9 percent (v/v), *Min*

**A-1.2.4 Internal Standard Stock Solution** — Dilute 5.0 ml of 1-propanol (see **A-1.2.2**) to 100 ml.

**A-1.2.5 Ethanol Stock Solution** — Dilute 5.0 ml of ethanol (see **A-1.2.1**) to 100 ml.

**A-1.2.6 Ethanol Standard Solution** — Take 10 ml of ethanol stock solution (see **A-1.2.5**) in a 100 ml volumetric flask, add 10 ml of internal standard stock solution (see **A-1.2.4**) and make up volume to 100 ml.

**A-1.2.7 Internal Standard Solution** — Dilute 5 ml of internal standard stock solution (see **A-1.2.4**) to 50 ml.

**A-1.2.8 Test Solution** — Take sample equivalent to 0.5 ml of ethanol (see **A-1.2.1**) in a 100 ml volumetric flask, add 10 ml of internal standard stock solution (see **A-1.2.4**) and make up volume to 100 ml.

**A-1.2.9 Methanol Stock Solution** — Dilute 5.0 ml of methanol (see **A-1.2.3**) to 100 ml.

**A-1.2.10 Methanol Standard Solution** — Take 5.0 ml of methanol stock solution (see **A-1.2.9**) in a 100 ml volumetric flask, add 10 ml of internal standard stock solution (see **A-1.2.4**) and make up volume to 100 ml.

## A-1.3 Procedure

**A-1.3.1** Set the instrument as per chromatographic condition as given in **A-1.1.1** above and allow the instrument till stable base line is achieved.

**A-1.3.2** Inject separately 2  $\mu\text{l}$  of each, ethanol standard solution, internal standard solution and methanol standard solution and determine the retention time of ethanol, 1-propanol and methanol.

**A-1.3.3** Inject 5 injections of ethanol standard solutions and calculate Relative Standard Deviation (RSD) of internal standard response ratio. RSD should be less than 2. Use average peak area of five injections for calculation.

**A-1.3.4** Inject 2  $\mu\text{l}$  of test solution in duplicate. Use average peak area of two injections for calculation.

## A-1.4 Calculation

Calculate ethanol content in sample as follows:

$$\text{Ethanol content, percent (v/v)} = \frac{R_2 \times W_s \times D \times 100}{R_1}$$

where

$R_2$  = peak ratio of ethanol to 1-propanol for sample solution;

$W_s$  = concentration of ethanol in standard solution in percent (*v/v*);

$D$  = dilution factor for sample solution; and

$R_1$  = peak ratio of ethanol to 1-propanol for standard solution.

#### **A-2 DETERMINATION OF ABSENCE OF METHANOL**

Observe the chromatograms obtained with test solution and methanol standard solution. Test complies if no peak observes, in the chromatogram obtained with test solution at the retention time of methanol.

## ANNEX B

(Foreword)

## COMMITTEE COMPOSITION

Cosmetics Sectional Committee, PCD 19

<i>Organization</i>	<i>Representative(s)</i>
Drugs Controller General (India), Delhi	DR V. G. SOMANI ( <b>Chairman</b> )
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CSIR Indian Institute of Toxicological Research, Lucknow	DR R. S. RAY
Department of AYUSH, Delhi	DR D. C. KATOCH
Directorate of Drugs Control, Kolkata	SHRI K. R. CHAWLA
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Mikasa Cosmetics Limited, Ahmedabad	Ms TRUPTI PATEL
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All India Cosmetic Manufacturers Association, Mumbai	MS KAJAL ANAND DR VIRENDRA V. CHAVAN ( <i>Alternate</i> )
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Dabur India Limited, Sahibabad	DR PRASUN BANDYOPADHYAY DR S. K. LUTHRA ( <i>Alternate I</i> ) SHRI SHIVAJI RAI ( <i>Alternate II</i> )
Directorate of Food and Drugs Administration, Goa	Ms JYOTI J. SARDESSAI Ms SHWETA DESSAI ( <i>Alternate</i> )
Drugs Control Department, Delhi	SHRI A. K. NASA SHRI K. R. CHAWLA ( <i>Alternate</i> )
Essential Oil Association of India (EOAI), Noida	SHRI YOGESH DUBEY SHRI PRADEEP KUMAR JAIN ( <i>Alternate</i> )

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Food and Drugs Administration Haryana, Panchkula	SHRI NARENDER KUMAR AHOOJA SHRI MANMOHAN TANEJA ( <i>Alternate</i> )
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Hygienic Research Institute Private Limited, Mumbai	SHRI M. B. DESAI DR JAYASHREE ANAND ( <i>Alternate</i> )
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*Member Secretary*

SHRIMATI. NISHA BURA  
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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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### **Amendments Issued Since Publication**

<b>Amend No.</b>	<b>Date of Issue</b>	<b>Text Affected</b>

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